Swords into plowshares
Leveraging clinical data quality excellence and data mining tools for promoting quality of care

Dr. Peter Pronovost, Sr. Vice President – Patient Safety and Quality, Johns Hopkins Hospital
Aloha McBride, Principal, Ernst & Young LLP
Marc Schulman, Executive Director, Ernst & Young LLP
David N. Hoffman, Chief Compliance Officer, Physician Affiliate Group of New York, P.C.
Course agenda and session topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speakers</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction and course objectives</td>
<td>All</td>
<td>1:30 p.m. – 1:35 p.m.</td>
</tr>
<tr>
<td>Why we need to start treating clinical data like financial data. A case study from Johns Hopkins, the value of data. Leveraging high reliability principles and financial management concept.</td>
<td>Dr. Peter Pronovost</td>
<td>1:35 p.m. – 2:20 p.m.</td>
</tr>
<tr>
<td>How do you begin to think about clinical data transactions like financial data transactions and governance: a quick overview of COSO, due diligence and ERM. How to begin to applying these concepts to clinical data quality and reporting integrity</td>
<td>Aloha McBride/ Marc Schulman/ Tamil Chellaiah</td>
<td>2:20 p.m. – 3:15 p.m.</td>
</tr>
<tr>
<td>Break</td>
<td>–</td>
<td>3:15 p.m. – 3:30 p.m.</td>
</tr>
<tr>
<td>Leveraging data mining/analytics to improve quality of care through the automated generation and distribution of actionable exception reports</td>
<td>David Hoffman</td>
<td>3:30 p.m. – 4:30 p.m.</td>
</tr>
</tbody>
</table>

Setting the stage on data — the never-ending struggle to determine the signal through noise

- Patient safety indicators are derived from administrative codes in billing and are broadly used in hospital ranking programs and pay-for-quality programs.
- Patient safety indicators are frequently inaccurate — missing many harms while also reporting false positives.
- Too often, hospital ratings and rankings reflect how well a hospital codes rather than how a hospital provides care.
- For instance, Johns Hopkins reduced the number of patient safety indicator (PSI) incidents it reported to CMS by 75%, thereby reducing its penalties.
- **However — only 10%** of the improvement resulted from changes in clinical care. The other **90% resulted from documentation and coding** that was more thorough and accurate.

Instead of using PSIs, there is an enormous need for valid and reliable measures that can be tested, controlled and audited, similar to financial transactions and measures.
Medical errors – why they occur and the role of clinical data integrity

Why do errors occur?
Commonly, errors are caused by systemic problems, including a lack of integrated process, technologies and governance that drive unwarranted variation.

What is at stake when clinical data contains errors?
- A patient’s life and livelihood
- Misdiagnosis/delayed diagnosis
- Medication errors
- Performance measurement calculation errors
- Reimbursement errors
- Trust in your organization’s ability to provide safe care

The problem with bad data

- Can result in inappropriate clinical decision-making and creates significant patient safety risk
- Impairs evidence-based medicine and coordination across the care continuum
- Increases the risk of beneficiaries not having access to covered services
- Can result in billing, payment and performance inaccuracies
- Produces inaccurate stakeholder reporting
- Erodes consumer trust and increases legal risk

HOW BAD DATA HURTS QUALITY IMPROVEMENT IN HEALTHCARE

Copy-paste use in EHRs cited for safety concerns
How does good data become bad information?

- Methods by which it is captured and stored — manual, incomplete, etc.
- Data and system architecture lacks interoperability, resulting in blind spots.
- Cultural roadblocks across the health system prevent collaboration.
- Integrity of systems is not adequately protected, allowing for vulnerabilities and workarounds.
- Clinicians and data scientists operate in silos so reporting is not relevant or actionable in the clinical setting.
- Lack of structure and controls in underlying clinical process to manage quality data inputs.

What is High Reliability Organizing (HRO) and how can it help us to improve clinical data integrity?

HRO is the pursuit of flawless performance under complex, dynamic and oftentimes, potentially catastrophic conditions.*

1. Sensitivity to operations
2. Deference to expertise
3. Reluctance to simplify
4. Preoccupation with failure
5. Commitment to resilience

*Source: Karl E. Weick and Kathleen M. Sutcliffe, Managing the Unexpected: Resilient Performance in an Age of Uncertainty
How have HROs organized for success? The advent of the Operating Management System

Unifying framework for structured assurance of safety, quality and reliability and an integrated approach for continuous organizational learning, innovation and improvement

For critical data, this means the utmost control, monitoring and testing to certify that all data sets are complete, accurate, interoperable, accessible, relevant and auditable.

What are the core components of an HRO operating model — a lesson from Johns Hopkins Medicine

Johns Hopkins' Operating Management System*

Governance supports a committee structure at every level of the organization — similar to a board finance and audit committee — the clinical quality committee has fiduciary duties to confirm clinical quality and safety — inclusive of clinical data integrity

*Johns Hopkins Medicine, Armstrong Institute for Patient Safety and Quality: Proprietary
Johns Hopkins Medicine – governance, leadership and accountability

- Board of Trustees (Board) confirms oversight for quality and safety
- Applies the same rigor as applied to finance
- High reliability is a specific strategic objective
- Strategic objectives flow consistently throughout the health system
- Quality, safety and service are key components of strategic objectives
- Each clinical area is accountable for performance in four standard domains (patient safety, experience, value and external reporting)
- Leaders create shared accountability that cascades from Board to bedside

### Shared leadership accountability

<table>
<thead>
<tr>
<th>Board</th>
<th>CEO</th>
<th>Presidents</th>
<th>Dept. heads</th>
<th>Unit leaders</th>
<th>Frontline</th>
<th>Patient</th>
</tr>
</thead>
</table>

Use the levers and adaptive leadership to strengthen the links

- Responsibility, role clarity and feedback
- Capacity
- Time and resources

Source: Weaver; J Healthcare Management In press
Rigorous reporting and monitoring of core quality and safety measures

The Board confirms that a framework for reporting quality and safety of care mirrors the rigor and comprehensiveness of a consolidated financial statement.

Driving accountability through proactive monthly and quarterly reporting and oversight

1. Performance below target for one month or one performance period (ex: one quarter)
   - Local champions to form performance improvement team
   - Review data and investigate defects
   - Identify barriers and implement targeted interventions

2. Performance below target for two months or two performance periods
   - PI team presents to local Hospital Quality Council and President/CEO
   - President meets with appropriate clinical director and PI team
   - President presents plan with timelines to JHM QSS executive committee

3. Performance below target for three months
   - Department Director/MD champion present to local hospital Quality and Safety Board (trustee chair and President sign QI plan)
   - President presents to JHM Quality Safety Board Committee
   - AI conducts peer-to-peer review

By monitoring clinical quality and safety, any small change in clinical pathway performance is noted, investigated and remediated thoughtfully and quickly — individuals are rewarded for anticipating, identifying and remediating clinical risks.
So – why are we concerned with clinical data quality and controls?

Health care organizations require complete, accurate, relevant and reliable patient safety, quality and performance data in order to make sound clinical decisions, support reimbursement documentation and meet their internal and external reporting requirements.

Questions to ponder…

► Do you have a “Board to the Bedside” governance structure for clinical quality and patient safety measures and risks?
► Are you managing and overseeing your clinical data with the same level of rigor as your financial data?
► Do you have risk and internal control(s) owners over your clinical processes, systems and data?
► How confident are you that the clinical data residing in your systems is complete, accurate, interoperable, accessible, relevant and auditable?
► Do you understand how each clinical data element traverses though all of your systems into clinical diagnosis decisions, revenue cycle and performance reporting?
► Are you regularly testing and independently auditing clinical data, diagnosis and coding to identify control gaps, compliance gaps and training gaps?
Health systems must proactively identify, understand and manage clinical risks … robust effective internal controls, monitoring and governance activities are crucial

<table>
<thead>
<tr>
<th>Health care risk themes</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant cost pressures</td>
<td>Increased regulatory requirements</td>
<td>Patient safety and quality concerns</td>
<td>Competitive market -- new business models</td>
<td>Growth of health insurance exchanges</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health care emerging risks</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>✮ Increased focus by consumers on safety/quality and patient experience</td>
<td>✮ The need to demonstrate ROI for technologies — that support safety, quality and patient care</td>
<td></td>
</tr>
<tr>
<td>✮ Increasing move toward evidence-based treatments and protocols and related reimbursement issues</td>
<td>✮ Increasing vertical integration throughout the health care value chain across traditional boundaries to deliver integrated care models</td>
<td></td>
</tr>
<tr>
<td>✮ The need to demonstrate efficiency, leading practice and continuous improvement</td>
<td>✮ Increased demand on IT systems for analytics, business intelligence and reporting</td>
<td></td>
</tr>
<tr>
<td>✮ Emerging market-driven delivery models (ACOs)</td>
<td>✮ Heightened focus on privacy and security lapses with the advent of mobile and digital platforms</td>
<td></td>
</tr>
<tr>
<td>✮ Increased regulations, government intervention and heightened compliance obligations</td>
<td>✮ Consumer-driven demand for performance information and consumer-driven performance feedback</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health care top issues</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>Health data/accuracy, security and use</td>
<td>CMS compliance</td>
<td>Regulatory adherence</td>
<td>Maximize revenue from activity</td>
<td>Meaningful use</td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td>Clinical innovation/ evidence-based care</td>
<td>Cost management and efficiency</td>
<td>Technology investments and value</td>
<td>Resource capacity/capability</td>
<td>Health insurance exchanges</td>
<td></td>
</tr>
</tbody>
</table>

To enable high reliability of clinical data, health systems must treat clinical data with the same rigor as financial data

Enterprise Risk Management (ERM)
ERM is a discipline that addresses the full spectrum of an organization's risks, including challenges and opportunities, and integrates them into an enterprise-wide, strategically aligned portfolio view. ERM contributes to improved decision-making and performance management and supports the achievement of an organization's mission, goals and objectives.

Internal Controls Management (ICM)
ICM is a process for promoting achievement of an organization's objectives in operational effectiveness and efficiency: reliable clinical performance reporting; and complying with laws, regulations and policies.

How do we quantify enterprise risks and design internal controls that matter?
The impact of a risk is quantified in terms of existing performance measures and is evaluated by gauging the potential volatility the risk has on strategic goals and related business outcomes. Internal controls are designed, monitored and tested against those key clinical processes that drive critical performance and compliance measures.

Why are ERM and ICM critical to HROs?
HROs must anticipate risk and mitigate harm in order to achieve mission success. In order to anticipate risk, health systems must have early warning and continuous monitoring systems in place to proactively address potential harms. ERM and ICM provide this capability and prescribe disciplined activities to root out data quality issues and test the reliability of performance and compliance reporting measures.
The basics – incorporating HRO into risk management and internal controls using the COSO internal controls framework to drive clinical quality and reporting integrity

- Leveraging the principles of enterprise risk management, internal controls and HROs can identify potential harms while improving clinical data quality and reporting
- Start by asking the simple question …

何 might we manage the integrity of clinical data as if it were financial data in order to reduce errors in diagnoses and potential patient harm?

As health care compliance and risk professionals — you understand the level of rigor and scrutiny applied to ticking and tying every invoice in order to maintain financial transparency and solvency — might we well do the same when someone’s life is at risk?

Integrating the five components of internal control with the five tenets of HRO enables organizations to action and adopt High reliability behaviors that drive toward zero harm.

COSO and HRO aligned – COSO provides a structured framework to assess the internal controls environment to identify potential risk which clearly is aligned to HRO

<table>
<thead>
<tr>
<th>Components of internal control</th>
<th>Principles of internal control</th>
<th>Alignment to high reliability tenets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Control environment</td>
<td>1. Demonstrates commitment to integrity and ethical values</td>
<td>Commitment to resilience</td>
</tr>
<tr>
<td></td>
<td>2. Board of Directors demonstrates independence from management and exercises oversight responsibility</td>
<td>Preoccupation with failure</td>
</tr>
<tr>
<td></td>
<td>3. Management, with board oversight, establishes structure, authority and responsibility</td>
<td>Deference to expertise</td>
</tr>
<tr>
<td></td>
<td>4. The organization demonstrates commitment to competence</td>
<td>Reluctance to simplify</td>
</tr>
<tr>
<td></td>
<td>5. The organization establishes and enforces accountability</td>
<td>Sensitivity to operations</td>
</tr>
<tr>
<td></td>
<td>7. Identifies and assesses risk</td>
<td>Sensitivity to operations</td>
</tr>
<tr>
<td></td>
<td>8. Considers the potential for fraud in assessing risk</td>
<td>Reluctance to simplify</td>
</tr>
<tr>
<td></td>
<td>9. Identifies/assesses significant change that could impact system of internal control</td>
<td></td>
</tr>
<tr>
<td>3. Control activities</td>
<td>10. Selects and develops control activities</td>
<td>Preoccupation with failure</td>
</tr>
<tr>
<td></td>
<td>11. Selects and develops general controls over technology</td>
<td>Sensitivity to operations</td>
</tr>
<tr>
<td></td>
<td>12. Deploys through policies and procedures</td>
<td>Deference to expertise</td>
</tr>
<tr>
<td>4. Information and communication</td>
<td>13. Obtains or generates relevant, quality information</td>
<td>Preoccupation with failure</td>
</tr>
<tr>
<td></td>
<td>14. Communicates internally</td>
<td>Commitment to resilience</td>
</tr>
<tr>
<td></td>
<td>15. Communicates externally</td>
<td>Reluctance to simplify</td>
</tr>
<tr>
<td>5. Monitoring</td>
<td>16. Selects, develops and performs ongoing and separate evaluations</td>
<td>Preoccupation with failure</td>
</tr>
<tr>
<td></td>
<td>17. Evaluates and communicates deficiencies</td>
<td>Deference to expertise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Commitment to resilience</td>
</tr>
</tbody>
</table>
What does an ERM- and ICM-enabled health care organization look like?

<table>
<thead>
<tr>
<th>Environment</th>
<th>Governance</th>
<th>Owners</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization is interested in and has the ability to assimilate external measures and market data to guide its performance and actions, e.g., social media and patient ratings.</td>
<td>The nature and amount of risk the organization is willing to tolerate are clearly articulated and understood and are utilized to drive allocation of capital.</td>
<td>Boards are provided with auditable, quality, meaningful data to guide investment and strategy decisions. They have &quot;Board to Bedside&quot; visibility of patient care outcomes.</td>
</tr>
<tr>
<td>Suppliers</td>
<td>Operators</td>
<td>Regulators</td>
</tr>
<tr>
<td>The organization understands its suppliers, and where the risk to patient safety and quality is within that supply chain. This is used to optimize a tailored supplier and supplies base.</td>
<td>All clinical processes consider the risk on patient outcomes.</td>
<td>The organization understands its reporting requirements, and confirms it is providing correct auditable quality safety, quality and performance data in line with compliance requirements.</td>
</tr>
<tr>
<td>People</td>
<td>Processes</td>
<td>Technology</td>
</tr>
<tr>
<td>A culture of &quot;Zero Harm,&quot; and a focus on patient risk and proven controls is embraced organization-wide.</td>
<td>All clinical processes consider the risk on patient outcomes.</td>
<td>Identification of clinical risk and management is embedded in the use of technology.</td>
</tr>
</tbody>
</table>

Competitors

The organization scans the competitor landscape to understand any threats to market or performance. The focus is always on delivery of care and how emerging competitors may impact the organization's ability to continue to provide quality services.

The Three Lines of Defense Model for clinical data

The Three LOD model — a standard approach in financial management — can be applied to clinical, safety and quality data. Such an approach sets the structure for clinical data to be treated with just as much rigor as financial data.

The Three Lines of Defense model confirms there is segregation between direct accountability for risk decisions, independent oversight and independent assurance on the effectiveness of risk management, control and governance processes.

Board

Sets the strategy and risk appetite of the organization

First line

Risk taking business units

- Are responsible for owning and managing risks in the business:
  - Develop and implement the strategy
  - Measure business performance
  - Implement internal control and risk management framework
  - Confirm that the business is managed within the agreed risk appetite

Second line

Compliance and risk functions

- Provides objective oversight of the management of risks by the business:
  - Design and deploy the overall risk management framework across the organization
  - Monitor adherence of the business to risk framework policies and procedures
  - Support and challenge the business on its management of risks and controls

Third line

Independent assurance and validation

- Provides independent assurance:
  - Independently assess and report on effectiveness of design and operation of the risk management framework
  - Carry out testing of key controls
  - Review activities performed by first and second LOD so that they are appropriately meeting their responsibilities
HRO’s aim to have clinical data and integrity auditing as standard activities using a similar LOD assessment and reporting model

Alignment of oversight responsibilities across the Board and committees

Integrated and consistent reporting

Risk-based clinical data auditing is included in the internal audit plan

Efficient risk and control management framework across the first, second and third Lines of Defense

Integrated risk and control assessments

Clear risk and control ownership in first Line of Defense (business)

Page 22

Leveraging an HRO-enabled risk and controls approach to drive clinical data integrity
**HRO-enabled enterprise risk and controls-based approach – stepwise approach**

1. **Understand the operating environment**
   - Understand current state performance, strategic objectives and HRO initiatives
   - What is the strategy to pursue zero harm — how effective are our initiatives?
   - Which clinical pathways are key to success?

2. **Customize Risk Universe™ and inherent risk profile**
   - Define inherent industry risks to achievement of goals:
     - Strategic
     - Operational
     - Financial
     - Compliance
     - Clinical

3. **Identify significant inherent risks**

4. **Map objectives to inherent risks and clinical processes**

5. **Assess internal controls design**
   - Assess the maturity and completeness of the internal controls design for those processes selected during the risk workshop through process walk-throughs with process owners.

6. **Plan and implement future state controls environment**
   - Collaborate with stakeholders to develop a revised risk and control matrix and finalize governance, roles, responsibilities, cadence for monitoring activities and reporting.
   - Develop and implement future state risk and control operating model.

---

**Step 1 – Understand the operating environment**

1. Understand current state performance, strategic objectives and HRO initiatives
2. What is the strategy to pursue zero harm — how effective are our initiatives?
3. Which clinical pathways are key to success?
4. Where is the organization on the HRO journey?
5. What are the goals and objectives?
6. What are the risk tolerance and appetite?
7. What is the current level of reporting maturity?
8. How are the audit committee and other governance bodies structured?
9. Which metrics are reported?
10. Who receives key reports?
11. Which systems are relied upon for this data and what is the chain of custodianship?
12. Are the supporting structures in place and do they align with the strategy?
13. What are they doing now to promote data quality?
14. Are there obvious weaknesses in these processes and controls?

---

Source: EY/Johns Hopkins Medicine Proprietary Methodology
Step 2 – Customize the inherent risk universe

<table>
<thead>
<tr>
<th>Strategic</th>
<th>Operational</th>
<th>Clinical</th>
<th>Compliance</th>
<th>Financial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance</td>
<td>New business</td>
<td>Patient engagement</td>
<td>Code of Conduct</td>
<td>Market</td>
</tr>
<tr>
<td></td>
<td>Tone of the organization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tone of the organization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Management of risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planning and measure alloc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employee and Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rating Agencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2 – Customize inherent risk universe</td>
<td>Perform a thorough risk inventory to identify those risks that are important to the objectives of the organization.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Step 3 – Identify areas of significant clinical quality and safety risk — sample risk areas and categorize across a threat matrix

Review the risk assessment to review and validate supporting and relevant data. Assess the key risk indicators and variance to compile a qualitative and quantitative assessment of the key risk areas.

Clinical
- Variations in service delivery related to demographic factors
- Incident database incomplete, inaccurate — potential for underreporting of events
- EMR incomplete, incorrect: misdiagnosis or incorrect treatment
- Errors in receipt of medications
- Delayed identification of service quality errors — i.e., undetected shafts in mortality/morbidity

IT
- Systems disparate: linkages are unstable
- Data entry predominately manual and by low-skilled teams
- Lack of clarity concerning the underlying analytics
- Insufficient cybersecurity measures — potential for safety and security breaches
- Underdeveloped business continuity planning for system shutdown

Compliance
- Risk of non-compliance with mandatory reporting resulting from poor data control
- Delayed action in addressing undiscovered issues

Safety and Quality
- Errors to patient laboratory data — slow/inaccurate reporting
- Primary care referral database out of date affecting patient handover and communication
- Incident reporting lag — three month turnaround: May result in repeat issues
- Medical record process manual — increased opportunity for errors

Goverance
- Performance reporting is static: consolidate three month — limited predictive value
- Undisclosed reporting and accountability structures in key areas

Workforce
- Rostering occurs separately from planned activity
- Significant churn in the administrative department resulting in operational disruption
**Step 4 – Link risk to clinical objectives and processes**

<table>
<thead>
<tr>
<th>Clinical objectives and initiatives</th>
<th>Inherent key clinical risks</th>
<th>Clinical processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experience:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governance:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health equity:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Clinical processes**

<table>
<thead>
<tr>
<th>Patient administration and data entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease, case and utilization management</td>
</tr>
<tr>
<td>Equipment and consumables ordering and training</td>
</tr>
<tr>
<td>Pathology collection, timing, handling</td>
</tr>
<tr>
<td>Incident management process and system</td>
</tr>
<tr>
<td>Medications management – prescribing, dispensing</td>
</tr>
</tbody>
</table>

**Step 5 – Assessment of internal controls design**

**Clinical process and control documentation**

**Process**
- Conduct risk-based process understanding interviews and walk-throughs for in-scope clinical processes
- Document clinical process risks, controls, gaps and relevant control information (owner, frequency, evidence, IT systems, etc.) in narratives, flowcharts and the Risk and Control Matrix (RCM)
- Develop remediation plans to address control gaps and other process and control design recommendations

**Output**
- Process narratives and/or flowcharts
- Risk and Control Matrix – i.e., controls to be implemented to address the identified risks
- Summary report of finding themes and recommendations, including organizational maturity in managing risk

Document process flows to visualize a process entirely. Aim to fully understand the process and pinpoint where risks, controls and gaps exist.

This also enables greater coordination with the process owners when validating understanding, and agreement.
### Step 6 – Future state internal controls design

**Process**
- The RCM developed in the previous phase will serve as a tool to evaluate current controls, to perform a gap analysis and to make recommendations regarding the design of new controls, where applicable.
- Controls are assessed so they are not excessive, in order to make the process as lean as possible. Any proposed improvements are aligned to the HRO principles and the organization’s objectives.
- Action plans are drafted then validated with the organization and refined.
- New controls are implemented. Assistance is provided to the organization to build the capability to implement controls.

**Output**
- Recommendations on the design of new controls and on the possible reduction of redundant controls
- Action plan including improvement opportunities in case of structural deficiencies we have identified
- A list of opportunities for simplification of controls where appropriate
- Assistance and guidance with the design/enhancement of controls, using the RCM as tracking tool
- Actions are performed in alignment with stakeholders, such as the process owners, in order for them to support and accept changes
- Development of longer-term test and audit program

---

### Step 6 – Controls become the “day-to-day” process for managing data integrity risks

**Risk management activities are embedded within the existing planning, analysis and reporting processes … known as the “rhythm of the business”**

- Board and board committee meeting
- Executive-level strategic planning
- Operational and business-level planning, utilize clinical communities/process improvement teams to plan and execute
- Monthly/quarterly performance reviews
- Continuous performance management and reporting
- Continuous compliance and risk assurance activities

---

**Strategic oversight and planning**

**Clinical area/or business area ownership, i.e., ICU/theatres community**

**Coordination of monitoring and compliance activities**
Where to go from here?
Potential next steps to consider for your organization

► Review your governance structure relative to clinical quality and patient safety performance metric ownership – do you have alignment from the “Board to the Bedside?”

► Understand your environment – select a critical care pathway (high demand, high revenue, clinically complex) and perform a clinical data element flow review and audit – where are your control gaps and what are your most frequent data errors?

► Start with your event reporting database and spot audit clinical data element flow and integrity across a near miss event.

► Interview your clinicians to understand where their clinical data pain points, concerns and workarounds relative to clinical data capture and analysis.

Opportunity awaits!

Improved data

Improved patient outcomes/ reduced rates of harm

Greater process quality, risk management and control

Bette understanding of process and patient threats

More informed decision-making
EY | Assurance | Tax | Transactions | Advisory

About EY

EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

Ernst & Young LLP is a client-serving member firm of Ernst & Young Global Limited operating in the US.

© 2017 Ernst & Young LLP. All Rights Reserved.

1706-2005459
ED None

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax or other professional advice. Please refer to your advisors for specific advice.

ey.com

15-minute break
Leveraging data mining and analytics to drive quality, compliance and risk reduction

What you will learn

► The solution is hiding in the record.
► Metadata is your friend.
But first, for some context

► First rule of corporate compliance:
  ► Don’t bill for care you didn’t provide.
  ► That’s stealing.

Some more context

► Second rule of corporate compliance:
  ► Don’t bill for care you provided that wasn’t necessary.
  ► That’s stealing.
And

Third rule of corporate compliance:
- Don’t bill for care you provided that was necessary but was of poor quality.
- That’s______________?

“Quality care” did not mean the patient got “all better.”

Doctors couldn’t and were not expected to guarantee outcomes.
With *Value-based purchasing*,

all that has changed.

Acronyms that have ruled our lives
HCAHPS

Hospital Consumer Assessment of Healthcare Providers and Systems

CAHPS

Consumer Assessment of Healthcare Providers and Systems
**DSRIP(P)**

Delivery System Reform Incentive Payment Program

---

**And now**

VBP

(a very special acronym)
VBP

Value Based Purchasing

MACRA

Medicare Access and CHIP (Child Health Insurance Program) Reauthorization Act of 2015
What is MACRA?

► The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is a bipartisan legislation signed into law on April 16, 2015:
► What does Title I of MACRA do?
  ► Repeals the Sustainable Growth Rate (SGR) Formula
  ► Changes the way that Medicare rewards clinicians for value of volume
  ► Streamlines multiple quality programs under the new Merit-Based Incentive Payments System (MIPS)
  ► Provides bonus payments for participation in eligible alternative payment models (APMs)

MIPS changes how Medicare links performance to payment

There are currently multiple individual quality and value programs for Medicare physicians and practitioners:

- Physician Quality Reporting Program (PQRS)
- Value-Based Payment Modifier
- Medicare HER Incentive Program

MACRA streamlines those programs into MIPS

- Merit-Based Incentive Payment System (MIPS)
MACRA implementation timeline

- Providers may not be certain which track they will fall into when reporting in 2017.
- Not much time for many providers to get involved in Advanced APMs.
- Performance period: Providers notified of track assignment.
- Payment adjustment: Based on track assignment.
- 2016: Final rule released.
- 2017: Providers may not be certain which track they will fall into when reporting in 2017.
- 2018: Merit Based Incentive Payment System (MIPS).
Now back to metadata
Two keys to survival

1. Data mining
2. Exception reports

Metadata as sword

Detection…
Metadata as sword

Detection…
Followed by extrapolation…

And then,

Repayment!
**Metadata as tool**

Surveillance,  
Followed by intervention,  
Followed by corrective action.

---

**A simple example**

Unread lab results,  
Or PAP smears.
A not-so-simple example

DVT prophylaxis

What does the future hold?
Electronic medical records (EMR)

Friend or Foe?

► Friend or Foe?
► It doesn’t matter.
EMR as a term paper

► Citation, not Plagiarism.

EMR as a term paper

► “Copy and Paste”
► Is a dangerous tool we actually don’t need
A wonderful challenge

Changing a flat tire on a bus …

… while the bus is moving.

Thank you!

► (Please complete your evaluation)